

## **REMARKS**

This amendment is responsive to the August 21, 2007 Advisory Action and February 1, 2007 Office Action. Applicants filed a Notice of Appeal on July 24, 2007, along with an Amendment and Response under 37 C.F.R. § 1.116, which included Applicants' Interview Summary of the telephonic interview held July 17, 2007. Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 are pending and under consideration.

### **I. AMENDMENTS TO THE SPECIFICATION**

The specification has been amended to include, as example 12, portions of the computer code that were submitted in the "Computer Program Listing Appendix" on the compact disc with the instant application when it was first filed. This computer code was specifically incorporated by reference into the specification in lines 25 and 26 of page 1 of the instant application. No new matter is introduced with this amendment. Entry of the amendments to the specification is respectfully requested.

### **II. AMENDMENTS TO THE CLAIMS**

Claims 14, 17, 20, 22, 39, 42, 45-47 and 58 have been amended, in pertinent part, to recite "identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures."

Support for the amendments to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 are found in the specification as originally filed, for example, page 5, lines 5-10; page 6, lines 15-17, as well as page 27, line 26, to page 28, line 17, which refers to processing steps 208 and 216 of the exemplary processing steps illustrated in Figure 2.

Support for the amendments to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 are further found in Figures 4A, 4B, 4C, and 4D which provide a cutoff threshold line 402 which identifies those 30 cM intervals of a respective genome (genotypic data structures) in the plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures. As explained on page 31, lines 20-21, of the specification, dotted line 402 represents a useful cutoff for analyzing the data, with the highest correlated ten percent of the genome being above the line.

Support for the amendments to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 are further found in column 5 of Table 3 on page 33 which lists thresholds of 19, 17, 4, 8, 2, and 11

percent that were used to identify genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures.

Support for the amendments to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 are further found in Figures 7-12 which each show a cutoff toggle that allows the user to select the cutoff position of the horizontal dashed line that appears in the main panel of each of these figures (*e.g.*, the line labeled 5% in Figure 10). As set forth in the “Input\_output\_dev.pm” module in the computer program appendix which was incorporated by reference on page 1, lines 21-27, of the specification, those genotypic data structures whose correlation score is in the top percentile specified by the cutoff value will appear above the horizontal dashed line and be considered hits in the manner reported in Table 3 on page 33. Applicants have incorporated the portions of the code from “Input\_output\_dev.pm” into the instant specification (*see* Section I above) that allow a user to select a cutoff percentage such that the one or more genotypic data structures in a plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality of genotypic data structures are identified. Specifically, corresponding to Figures 7-12, in the exemplary computer code from “Input\_output\_dev.pm”, the user defines parameters for display, calculate, correlate, cutoff, and window. In this exemplary code, “Cutoff” may be assigned a value of 5%, 10%, 15%, 20%, 25%, 30%, 40% or 50%. *See* Amendments to the Specification (“PRINT THE CUTOFF POPUP MENU”) and Section I, above. Computer code from the file further contains instructions for displaying the cutoff line that is found in any of Figures 7-12. *See* Amendments to the Specification (“DRAW PCT CUTOFF LINE”) and Section I, above. Specifically, the aforementioned computer code displays the image of a dashed line at the ‘cutoff’ position that was selected by the user using the toggled identified in Figures.

Claims 14, 17, 20, 22, 39, 42, 45-47 and 58 have been amended, in pertinent part, to recite, in pertinent part, “communicating said one or more genotypic data structures to a user, a display, a readily accessible computer memory or other computer on a network.” Support for the amendment is found in the specification as originally filed, for example, by Figure 1 and accompanying description on page 10, line 22, to page 11, line 33, where, for instance, a user interface 24, display 28, storage unit 34, system memory 38, and a network interface card 36 for connecting to a communication network are provided. The operation of the subroutines are exemplified in connection with the description for Figure 2. An exemplary

user interface is illustrated in Figures 7-10 as discussed in the specification from page 28, line 18, to page 30, line 6.

The amendments to the claims are fully supported by the specification, drawings and claims as original filed. No new matter is introduced with these amendments. As such, entry of the instant amendments to the claims is respectfully requested.

No claim amendment fee is believed to be due since the numbers of independent and total claims have not been changed in the instant amendments.

### **III. ADVISORY ACTION OF AUGUST 21, 2007**

In the Advisory Action of August 21, 2007, the Examiner states that Applicants' proposed amendment to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 to recite "identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures" would introduce New Matter. Applicants disagree. For instance, this language tracks the specification, such as lines 5-10 on page 5, stating "one or more genotypic data structures are identified that form a high correlation value relative to all other genotypic data structures." The specification provides how the one or more genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures are identified, for example, by ranking the correlation scores (*see* page 27, line 28, to page 28, line 1) or, for example, by selecting genotypic data structures that form a correlation value that is a predetermined number of standard deviations above a mean correlation value (*see* page 28, lines 3-17) or, for example, by selecting a cutoff value using the exemplary code provided in the application as described in Section II above and as illustrated by the cutoff toggle in Figures 7-12. As such, the amendment in question is fully supported by the specification and claims as filed. For these reasons, the proposed amendment to claims 14, 17, 20, 22, 39, 42, 45-47 and 58 to recite "identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures" is not New Matter.

### **IV. CLAIM REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

In the February 1, 2007 Office Action, the Examiner rejected claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, as allegedly being

indefinite on the basis that these claims recite, or depend from a claim that recites, two separate phrases.

In the Advisory Action dated August 21, 2007, the Examiner states that claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 “are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. . . . If entered, applicants proposed after final amendment would be sufficient to overcome this rejection.” Nonetheless, Applicants arguments from the Amendment and Response filed July 24, 2007, are reiterated below so that they be made of record in the instant application.

**A.     The rejection should be withdrawn with respect to the phrase “said plurality of genotypic data structures that are not in said one or more genotypic data structures”**

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite on the basis that these claims lack, or depend from a claim that lacks, antecedent basis for “said plurality of genotypic data structures that are not in said one or more genotypic data structures.” The Examiner alleges that this phrase lacks sufficient antecedent basis because the claims do not recite any limitation or step drawn to identifying or determining a set of genotypic data structures that are not in the group of genotypic data structures. In response, Applicants have amended the phrase identified by the Examiner so that it now recites “said plurality of genotypic data structures.” Thus, the rejected claims no longer recite “that are not in said one or more genotypic data structures.”

On page 3 of the February 1, 2007 Office Action, the Examiner states that “[t]here is insufficient antecedent basis for this limitation in the instant claims, as the claims do not recite a limitation or step drawn to identifying or determining a set of genotypic data structures that are not in the group of genotypic data structures resulting from the previously recited step of ‘repeating said establishing and determining steps’ in the instant claims.” Applicants believe that amendments to the claims so that they now recite “identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures” address the Examiner’s concern. The claims as amended require identification of one or more genotypic data structures in a plurality that have higher correlation values than all other genotypic data structures in the plurality.

On page 3 of the February 1, 2007 Office Action, the Examiner further states that “the instant claims fail to provide a step wherein the correlation values are determined or established for genotypic data structures that are not in the group of genotypic data structures resulting from the previously recited step of ‘repeating said establishing and determining step.’” Applicants respectfully point out that the recited repeating step in Applicants’ claims results in the computation of a correlation value for each genotypic structure in the plurality of genotypic structures, including (i) the genotypic structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality of genotypic data structures and (ii) the genotypic structures that have correlation values that are not higher than the correlation values for all other genotypic data structures in the plurality of genotypic data structures. This is necessarily so because the repeating step repeats the establishing and determining step for each locus in the plurality of loci, thereby establishing the plurality of genotypic data structures in the first place and, for each such genotypic data structure, a correlation value. The identifying step then identifies one or more genotypic data structures from this plurality of genotypic data structures that have correlation values that are greater than the correlation values for all the other genotypic data structures in the plurality of genotypic data structures.

Each genotypic data structure has a correlation value that defines its correlation to a phenotypic data structure. Therefore, in accordance with the identifying step of, for example, claim 14, it is possible to rank all genotypic data structures in the plurality of genotypic data structures using the correlation values to a given phenotypic data structure, as taught on page 27, lines 26-31, of Applicants’ specification. As taught on page 28, lines 8-17, of the specification, in conjunction with step 216 of Figure 2, once the ranking process is finished, the genotypic data structures that are ranked in the top of the list would be the one or more genotypic data structures in the plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality of genotypic data structures.

In one embodiment, a cutoff value, shown as element 402 in Applicants’ Figures 4A-4D and described on page 31, lines 22-23, of the specification, identifies the one or more genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality of genotypic data structures.

Claims 15, 17, 20-22, 39, 40, 42, 45-47, and 58 as amended either recite or depend from a claim that determines correlation values in the same way as claim 14, as amended, and are therefore patentable for at least the same reasons that claim 14 is patentable.

Accordingly, the rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

**B. The rejection should be withdrawn with respect to the phrase “high correlation value”**

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 stand rejected under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis for the recitation of the phrase “a high correlation value relative to the correlation values of genotypic data structures that are not in said one or more genotypic data structures.” On page 3 of the February 1, 2007 Office Action, the Examiner contends that “the use of the relative term ‘high correlation value’ is indefinite as neither the instant claims nor the instant specification provide a requisite threshold for when a given correlation value is to be considered a ‘high correlation value.’”

In response, Applicants have amended the rejected claims so that the phrase “high correlation value” is no longer recited. For example, claim 14 has been amended to recite “identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures.” As noted in Applicants’ comments in sections III.A, above, the amended claim language has sufficient antecedent basis.

Moreover, the specification provides ample teaching for the selection of the one or more genotypic data structure in the plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality. For example, page 28, lines 8 to 11, of Applicants’ specification states:

In processing step 216, the genotypic data structures that achieve the highest correlation values are selected. Since each genotypic data structure corresponds to a particular locus in the genome, the selection process in processing step 216 results in the association of the phenotype with particular loci in the organism of interest.

Also, page 28, lines 11 to 14, of the specification states that genotypic data structures that form a correlation value that is a predetermined number of standard deviations above the

mean correlation value are selected. Page 28, lines 15 to 17, of Applicants' specification explains that, in one embodiment, the predetermined number is chosen so that a small percentage of the genome of the organism, such as five percent, will be selected. Additional examples of the choices of one or more genotypic structures that have higher correlation values provided in Applicants' specification include "a genome-wide threshold of ten percent" and a percentage that ranges "from two percent to nineteen percent of the complete mouse genome." See page 34, lines 5-6 and line 16, respectively, of Applicants' specification. Further, the last column of Table 3 beginning on page 33 of Applicants' specification clearly illustrates the thresholds needed (*e.g.*, the choice of the one or more genotypic data structures that have correlation values that are higher than the other correlation values in the plurality) to identify a small percentage of the genome of the organism varies with respect to a specific phenotype that is being analyzed (*e.g.*, threshold values of 19, 17, 8, 4, and 2 percent are needed). Further examples of suitable choices for the one or more genotypic data structures that have correlation values that are higher than the correlation values of all other genotypic data structures are found in Figures 7 through 12 of Applicants' specification. For example, Figure 7 demonstrates that a cutoff value may be chosen to select, for example, a cutoff value of 5%. This means that the top 5% of the genotypic data structures in the plurality of genotypic data structures are selected as the "one or more genotypic data structures" based on correlation values. A toggle function, as depicted in Figure 7, allows the cutoff value to be adjusted according to the type and size of the genotypic data structures. Indeed, as discussed in Section II above, the exemplary computer code filed with the instant application, and incorporated by reference into the specification in lines 25-26 of page 1 of the instant specification, provides functionality for the user to adjust the toggle function to the other values (*e.g.*, 5%, 10%, 15%, 20%, 30%, 40% or 50%). The cited examples clearly demonstrate that the proper choice for the one or more genotypic data structures that have correlation values that are higher than the other correlation values in the plurality differs on a case by case basis.

Based on preceding analysis and examples, Applicants respectfully submit that the phrase "identifying one or more genotypic data structures in said plurality of genotypic data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in said plurality of genotypic data structures" provides a suitable and concrete definition of the metes and bounds of the instant claims. As such, Applicants believe that claims 14, 17, 20, 22, 39, 42, 45-47, and 58 are patentable.

In light of the claim amendments and these comments, Applicants respectfully request that the 35 U.S.C. § 112, second paragraph, rejection of claims 14, 17, 20, 22, 39, 42, 45-47, and 58 be withdrawn.

**V. CLAIM REJECTION UNDER 35 U.S.C. § 101**

The Examiner has rejected independent claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 101 because the claims are allegedly directed to non-statutory subject matter. In the Advisory Action dated August 21, 2007, the Examiner states that claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 “are rejected under 35 U.S.C. § 101 as being directed towards non-statutory subject matter. If entered, applicants amendment would be sufficient to overcome this rejection.” Nonetheless, Applicants arguments from the Amendment and Response filed July 24, 2007, are reiterated below so that they may be made of record in the instant application.

On page 9 of the February 1, 2007 Office Action, the Examiner stated that the 35 U.S.C. § 101 rejection could be overcome by amending the communicating step to recite “communicating said one or more genotypic data structures to a user, a display, a readily accessible computer memory or other computer on a network.” Applicants have amended claims 14, 17, 20, 22, 39, 42, 45-47, and 58 to recite this communicating step. In light of the claim amendments and the above comments, Applicants respectfully request that the 35 U.S.C. § 101 rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 be withdrawn.



**CONCLUSION**

Applicants respectfully request that the present remarks be made of record in the instant application.

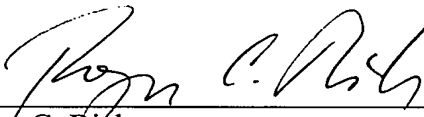
In view of the above remarks, Applicants respectfully submit that the subject application is in good and proper order for allowance. Withdrawal of the Examiner's rejections and objections and early notification to this effect are earnestly solicited.

No fees, other than those for the Petition for an Extension of Time and for the Request for Continued Examination, are believed to be due. However, if any fees are due in connection with this submission, please charge the required fees to Jones Day Deposit Account No. 50-3013 (order no. 800935-999015).

Respectfully submitted,

Date:

10/9/07

  
\_\_\_\_\_  
Roger C. Rich  
For: Thomas E. Friebe (Reg. No. 29,258)

54,398  
(Reg. No.)

**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, New York 10017-6702  
(212) 326-3939